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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/721,645

11/25/2003

Yatin Gokarn

3598/1/US

7427

26648

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05/02/2006

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GLOBAL PATENT DEPARTMENT  
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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/721,645

Applicant(s)

GOKARN, YATIN

Examiner

Patrick T. Lewis

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Newly submitted/amended claims 15 and 17-19 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the application contains two inventions (1. composition comprising a liquid carrier, valdecoxib, and a cyclodextrin and 2. a method of treating a disorder mediated by COX-2.) Inventions 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case treatment of a COX-2 mediated disorder such as arthritis may be treated using nutritional supplements containing gamma linolenic acid as taught by Florio U.S. Patent No. 5,840,715.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15 and 17-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Information Disclosure Statement***

2. The listing or citing of references in applicant's response is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

***Applicant's Response Dated February 9, 2006***

3. Claims 1-15 and 17-19 are pending. Claims 15 and 17-19 are drawn to a nonelected invention. An action on the merits of claims 1-14 is contained herein below.

4. The rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons of record as set forth in the Office Action dated August 9, 2005.

5. The rejection of claims 15-17 under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been rendered moot in view of applicant's amendment dated February 9, 2006.

***Rejections of Record Set Forth in the Office Action Dated August 9, 2005***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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7. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the text "wherein the cyclodextrin...at the given temperature" renders the claim and all subsequent dependent claims indefinite as it is unclear what the makeup of the pharmaceutical composition is. Applicant has failed to particularly point out what "a substantial portion of the valdecoxib" is. The ambiguity of the claim is further heightened because the amount of valdecoxib solubilized is described in relative terms. The amount of valdecoxib solubilized is in comparison to a "substantially similar composition"; however, applicant has failed to particularly point out what a "substantially similar composition" is. Furthermore, it appears from said text that applicant is comparing the solubilities of compositions comprising less than 5% w/v cyclodextrin to compositions comprising up to 95% w/v cyclodextrin. In the absence of a distinct definition of "substantially similar composition", one of ordinary skill in the art would not view these compositions as "substantially similar", as it is well known in the art that the solubility properties of cyclodextrins are concentration dependent.

Claims 6, 8-9 and 14 incorporate the phrase "the cyclodextrin is an  $\alpha$ -cyclodextrin and/or a  $\beta$ -cyclodextrin", "the cyclodextrin is a sulfoalkyl ether cyclodextrin and/or a hydroxyalkyl- $\beta$ -cyclodextrin", or "the cyclodextrin is a sulfobutyl ether cyclodextrin and/or a hydroxypropyl- $\beta$ -cyclodextrin". There is no antecedent basis for this limitation as claim 1 is limited to "a cyclodextrin".

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8. Applicant's arguments filed February 9, 2006 have been fully considered but they are not persuasive. The examiner disagrees with applicant's characterization of the instant rejection. The issue in claim 1 is not "open-ended" language, but rather applicant's failure to particularly point out and distinctly claim the instant composition. As set forth in the Office Action dated August 9, 2005, the instant composition is described in relative terms; however, applicant has failed to adequately describe composition used in the comparison or the amount solubilized valdecoxib present in the compound. There is nothing inherently wrong with using the term "substantial"; however, the term is treated and evaluated just like any other claim limitation in regards to what it conveys to one of ordinary skill in the art at the time of the invention. In the instant case, the claimed pharmaceutical composition is defined relative to "a substantially similar composition"; however, applicant fails to define what a "substantially similar composition" is. In claim 1 two compositions are compared—1. a composition wherein the cyclodextrin is present in an amount of not less than 5%, w/v, of the composition (>5%) and 2. a composition wherein the cyclodextrin comprises less than 5%, w/v, of the composition (<5%). The use of cyclodextrins to enhance the solubility of pharmaceutical drugs was well known in the art at the time of the instant invention. In regards solubility properties, one of ordinary skill in the art would not consider a composition containing 3% cyclodextrin as being "substantially similar to" a composition containing 85% cyclodextrin. Applicant fails to distinctly set forth a clear description or definition of what a substantially similar composition is in the specification. In the absence of a claim limitation that more distinctly sets forth the identity of the

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instant composition, one of ordinary skill in the art would not be apprised of the metes and bounds of the invention.

In regards to claims 6, 8-9 and 14, the cyclodextrin is limited to a single cyclodextrin and does not allow for mixtures. In lines 1-2 of claim 1, the composition contains "a cyclodextrin". Lines 3-4 further define "the cyclodextrin". There is no antecedent basis for "the cyclodextrin" being a mixture of cyclodextrins.

### ***Conclusion***

9. Claims 1-15 and 17-19 are pending. Claims 15 and 17-19 are drawn to a nonelected invention. Claims 1-14 are rejected. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

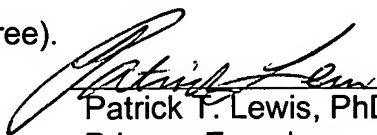
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patrick T. Lewis, PhD  
Primary Examiner  
Art Unit 1623

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